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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/806,295

03/22/2004

Paulo LaColla

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04/12/2007

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EXAMINER

WILLIAMS, LEONARD M

ART UNIT

PAPER NUMBER

1617

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/806,295	Applicant(s) LACOLLA ET AL.	
	Examiner Leonard M. Williams	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-24, 27-46 and 49-64 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 57-65 is/are allowed.
- 6) ☒ Claim(s) 19-24, 27-46 and 49-56 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

Detailed Action

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/03/2007 has been entered.

Response to Amendment/Arguments

The amending of claims 57-64 to independent claims is sufficient to overcome the objection of said claims as detailed in the prior office action.

The applicant's have amended claims 23, 31-44 and 46 to correct typographical errors and to include a definition of variable m.

New claim 65 has been added.

Claims 25-26 have been withdrawn.

Claims 47-48 have been canceled.

The applicants argue on page 48 of the remarks that one would not predict that compound M3 would be more active than the parent compound based on the initial decrease in activity when the sulfur is oxidized to the sulfoxide M1. The examiner

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wishes to note that the reference discloses both compounds and their relative activities as regards the parent compound. While the reference may teach that the sulfoxide M1 is less active than the parent and that the sulfone M3 is more active one of ordinary skill would only interpret this as the sulfone is important in increasing activity while the sulfoxide is not. Thus one would be motivated evidentially to pursue compounds that contain the sulfone moiety over the sulfoxide moiety. The applicants then assert that the di-substitution of the phenyl of the indole ring results in diminished activity as compared to the parent (M2A and M2B). The examiner respectfully points out that it is appropriate to compare the parent compound to M3, the parent compound to M2A, and the parent compound to M2B, as the comparative compounds consist of only one change in the molecule and thus provide valid structure-activity relationship (SAR) information. As M3 contains the sulfone moiety which shows increased activity over the parent compound, it does not hold that any additional changes to the parent (non-sulfone) compound would extend to the M3 compound. Thus one of ordinary skill in the art should not draw **any conclusions** regarding the changing of substituents on the M3 compound based upon what was seen in the parent compound from which M3 was derived.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does

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not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

The amendments to the claims do not overcome the 103(a) rejection of the previous office action and thus the rejection is maintained and included below.

Claims 57-65 appear to be free of the art.

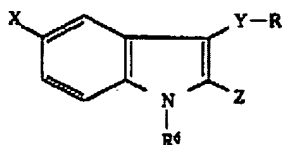
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-24, 27-46, 49-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (USPN 5527819).

Williams et al. teaches inhibitors of HIV reverse transcriptase for the treatment of HIV infection with the formula:



R is taught to be an aryl with the same substituents as claimed. Y is taught to be S(O)_n or O, as claimed. Z is selected from various amides, imines, etc., as claimed. R₆ is taught to be selected from, e.g., hydrogen, as claimed. X is taught to be selected from

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H, Cl, F, BR, etc., as claimed. Treatment of HIV in combination with other anti-HIV agents is also taught. See Abstract; col. 1, line 14-col. 15, line 23. Williams et al. does not teach at least one of R^{4'}, R^{6'} or R^{7'} as a non-hydrogen atom.

It would have been obvious to one of ordinary skill in the art to utilize a compound, as claimed wherein R^{4'}, R^{6'} or R^{7'} is a non-hydrogen because adjacent homologs are considered to be obvious absent unexpected results (*In re Henze*, 85 USPQ 261, 263 CCPA 1950) and members of a homologous series must possess unexpected properties not possessed by the homologous compounds disclosed by the prior art. *In re Hass*, 141 F.2d 127, 60 USPQ 548 CCPA 1944. *In re Hass*, 141 F.2d 127, 60 USPQ 548 (CCPA 1944); *In re Henze*, 85 USPQ 261 (CCPA 1950). In the instant case Applicant has claimed adjacent homologs to those taught in Williams et al. because Applicant's claimed invention encompasses a treatment wherein any one of R^{4'}, R^{6'} or R^{7'} is a methyl group or an halo group. With the teaching of Williams et al., one of ordinary skill in the art would expect to achieve at least similar results in the treatment of an HIV infection with the compounds of the invention disclosed therein when one of hydrogen atoms at the 4, 6 or 7 positions of the indole group are substituted with a methyl or halo group. Furthermore, it is noted that since Williams et al. teaches the treatment of HIV in general, it would have been obvious to one of ordinary skill in the art to treat specific instances of HIV, including those as claimed.

It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results

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should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

Conclusion

Claims 57-65 appear to be free of the art.

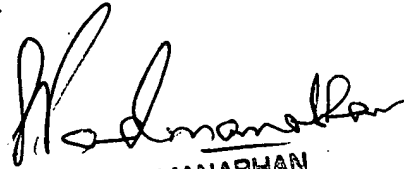
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M. Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LMW



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER